NONTECHNICAL ABSTRACT OF PROTOCOL

Many patients have advanced cancer that does not respond to standard therapies. For these patients, a new approach to treat their cancer (tumor) will be tested. Animal studies have been done using either cancer cells or their own skin fibroblast cells into which a cancer fighting gene has been placed. When these modified cells are returned to the animal the animal can "learn" to fight the cancer cells better. The return of the gene modified cells can be helpful in fighting cancer in several ways.

1. Injecting the patient's own skin cells (fibroblasts) right next to the tumor has been shown to reduce the size of tumor when these cells were genetically engineered to express cancer fighting genes. At the same time, this treatment has been shown to increase the responses of the animal's white cells in fighting the tumor cells as well.
2. Before returning fibroblasts to the patients, they will be altered to release a potent white cell activating factor (interleukin 12) by placing both the genes required to produce interleukin-12 into them. If these gene modified cells are used, the release of interleukin-12 by fibroblasts will increase the ability of the animal's white cells to fight cancer cells by activating the patient's own white cells.

This protocol is designed to mimic the results obtained with animals.
Patients with cancer who have not responded to other therapy will have a piece of skin cut out and brought to the laboratory. In the laboratory, the interleukin-12 gene will be put into the patient's normal cells (fibroblasts) grown from the skin. The fibroblasts are then injected right next to the tumors existing in the skin of the patient. This injection will be repeated once a week for four times in total. During this time and afterwards the patient is watched for signs that the therapy might be helpful in destroying their cancer. Since this therapy is new, it is not known how well it will work in people. The patients will also be watched for possible harmful effects from the therapy. After patients with several different kinds of cancer have received this new therapy, we will be able to determine how safe this new therapy is and begin to assess how well it works.